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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,212	04/05/2001	Ying-Fei Wei	1488.1280006	3523

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	09/826,212	WEI ET AL.
	Examiner Eileen O'Hara	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 December 2002 .

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 117-220 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 117, 120-175, 191-197, 199, 201 and 203-209 is/are allowed.

6) Claim(s) 176-190 and 210-220 is/are rejected.

7) Claim(s) 118, 119, 198, 200 and 202 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                            5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,10,11 .                            6) Other: \_\_\_\_\_ .

**DETAILED ACTION**

1. Claims 117-220 are pending in the instant application. Claims 23-116 have been canceled and claims 117-220 have been added as requested by Applicant in Paper Number 9, filed Dec. 27, 2002.

***Priority***

2. Applicants' amendment to the specification to update the priority claimed is acknowledged.

***Information Disclosure Statement***

3. The sequences disclosed in the IDS filed Oct. 2, 2001 (and duplicate received Dec. 27, 2002, references AT-3 to AR-8) have been considered to the extent that was possible absent an explanation of relevance or a sequence alignment.

***Withdrawn Objections and Rejections***

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

***Claim Objections***

5.1 Claims 198, 200 and 202 are objected to because of the following informalities: they are missing the word "sequence" after "amino acid".

5.2 Claims 118 and 119 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 118 and 119 do not further limit the polypeptide of claim 117, because claims 118 and 119 add on amino acids to the polypeptide of claim 117.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Newly added claims 176-190 and 210-220 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Action, Paper No. 8, at pages 4-5, and below.

Applicants traverse the rejection and assert that in an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability, and that the Examiner has not meet this burden. Applicants cite *in re Wertheim, Amgen, Inc. v. Chugai Pharmaceutical Co., Vas-Cath Inc. v. Muhurkar*,

*Union Oil Company of California v. Atlantic Richfield Company and University of California v. Eli Lilly*, as support for their position that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed, and that all of the objectives met by a generic chemical formula are similarly met by the explicit description in the instant specification of a polynucleotide sequence (SEQ ID NO: 1) and the amino acid sequence encoded thereby (SEQ ID NO: 2), various smaller fragments of the protein, and polypeptides consisting of at least 30 to 50 amino acids of SEQ ID NO: 2, and polypeptides having a recited percent identity to SEQ ID NO: 2. Applicants further argue that the skilled artisan could clearly envision each of the polypeptides comprising at least 30 contiguous amino acids of SEQ ID NO: 2 as a progression, and that the skilled artisan would certainly further envision sequentially adding contiguous amino acids to either end of any of the described embodiments, and the skilled artisan could also easily substitute or delete any given amino acid to achieve amino acid sequences that are at least 90% or 95% identical to the amino acid sequence of SEQ ID NO: 2. Applicants assert that because the claims recite amino acid molecules which consist of portions of the amino acid sequence of SEQ ID NO: 2 and the claimed variant polypeptides bind an antibody with specificity for a reference polypeptide consisting of SEQ ID NO: 2, the claims do not read on undescribed amino acid sequences. Applicants assert that under the Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, “Written Description”, a representative species may be adequately described through its structure, through its functional characteristics, or through a combination of its structure and function, and that the polypeptides embodies in the new claims are described by

both a structure and a functional characteristic, and that the recitation of the primary structure of the polypeptide and the functional test defines a genus and indicates possession of the genus.

Applicants' arguments have been fully considered and are deemed persuasive for polypeptides 90% to 95% identical to the polypeptide of SEQ ID NO: 2, and for polypeptides comprising the major domains of the polypeptide that have the activity of binding TRAIL (for example claim 191). However, they are not deemed persuasive for claims encompassing polypeptides comprising 30 or 50 contiguous amino acids or the transmembrane domain of the polypeptide of SEQ ID NO: 2. While the written description guidelines indicate that a molecule may be adequately described through a combination of structure and function, the degree of structure recited must also be considered. Following Applicants' arguments, a polypeptide comprising 10, 5 or even 2 amino acids of the polypeptide of SEQ ID NO: 2 would also be adequately described, as long as the polypeptide bound an antibody with specificity for a reference polypeptide consisting of SEQ ID NO: 2, and these polypeptides require virtually no structure. There is no specific cutoff for the amount of structure that is required to meet the written description guidelines, but enough structure should be recited to demonstrate possession. For example, 19 out of 259 amino acids (the transmembrane domain), is only 7% of the full-length protein, and does not provide adequate structure to meet the written description guidelines. Therefore, the rejection is maintained.

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It is believed that all pertinent arguments have been answered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 202 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 202 is indefinite because it encompasses a polypeptide wherein said first amino acid sequence is (c), but it depends from claims 197 and 196, which are drawn to the amino acid sequence of (b). The Examiner believes that Applicants intended claim 202 to depend from claim 200. Applicants should also check claim 203 for the correct dependency.

***Conclusion***

- 8.1 Claims 117, 120-175, 191-197, 199, 201 and 203-209 are allowed.
- 8.2 Claims 176-190 and 210-220 are rejected.
- 8.3 Claims 118, 119, 198, 200 and 202 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



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